

**DETAILED ACTION**

1. Claims 45-50, 52-56, 58, 59, and 61-65 are pending in the application.
2. In the prior action, mailed on December 1, 2009, claims 45-50, 52-56, 58, 59, and 61-65 were pending in the application; with claims 48, 52-56, and 63-65 withdrawn from consideration; and claims 45-47, 49, 50, 58, 59, 60, and 62 under consideration and rejected.
3. In the Response of March 30, 2010, the Applicant amended claims 45, 46, and 63-65.
4. Claims 45-47, 49, 50, 58, 59, 61, and 62 are under consideration.

***Information Disclosure Statement***

5. The information disclosure statements (IDS) submitted on November 25, 2009 and on January 22, and April 28, 2010 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Certain references in the IDS listings have been crossed out. These references were previously made of record and considered.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **(Prior Rejection- Maintained)** Claims 45-47, 49-50, 58, 59, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/068257 (WO'257) as previously applied further in view of Huber et al. (Cancer Res 40:3484-90).

The Applicant traverses the rejection on the basis that Huber refers to a bi-phasic immune response, and not to a persistent immune cycling as required by the present claims and identified by the teachings of the application. The argument is not found persuasive. The reference suggests at pages 3485 and 3489 that there is a continued cycling of cytolytic and suppressive immune cells in immune responses in animals. While the reference does not actually show continued cycling beyond a first cytolytic phase, a first suppressive phase, and an additional cytolytic phase; this appears to be due to the deaths of the animals being monitored rather than an indication that the cycling terminates after these three phases.

Based on such teachings, and the teachings of the WO reference previously applied indicating the benefits of administering certain agents at time points where the suppressor cells begin to become more active (i.e. at the initiation of the suppressive phase of the immune response cycle), it would have been obvious to those of ordinary skill in the art to apply the knowledge of such cycling to predict the most opportune timing for repeated administrations of the agents of the WO reference by first monitoring the patient to determine the approximate timing of the various phases in the cytolytic/suppressive activity cycle. It would have been apparent from the teachings of Huber indicating the existence of such cycling, that repeated administrations of the agents that inhibit the suppressor cell activity would be required (i.e. at each point where the nature immune cycling would result in increased activity by such cells).

Thus, the combined teachings of the references would have suggested the presently claimed method.

For these reasons, and for the reasons of record, the Applicant's arguments and amendments are not found persuasive.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. **(Prior Rejection- Withdrawn)** Claims 45-47, 49-50, 58, 59, 61, and 62 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 33-35, 37, 38, and 45-47 of copending Application No. 10/503794 in view of the teachings of Huber. No arguments have been presented with respect to the rejection. However, as the present claims now require a prior monitoring and determination of the immune cycle to determine when an agent is to be administered in the future, whereas the

copending claims require the administration of the agent when a specific sample indicates that suppressor cells are becoming or are about to become more active, the rejection is withdrawn.

10. **(Prior Rejection- Maintained)** Claims 45-47, 49-50, 58, 59, 61, and 62 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 10-13, and 15 of copending Application No. 12/233/369 in view of Huber. As no argument has been presented with respect to the present rejection, and as it is not Office policy to hold such rejections in abeyance, the rejection is maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

11. No claims are allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/  
Primary Examiner, Art Unit 1648